

REMARKS

In the Office Action dated June 27, 2007, Examiner Ramana rejected claims 37-52 and 55-65 as being allegedly anticipated, and affirmed her withdrawal of claims 1-36, 53-54 and 66-67 from her further consideration. In this amendment, claims 1-36, 41, 50, 53-54, 63 and 66-67 have been cancelled without prejudice to reconsideration in this or a continuing application, in order to move this application more quickly toward allowance. No admission is made concerning the patentability of any claim or subject matter therein. Claims 37-40, 42-49, 51-52, 55-62 and 64-65 remain pending.

It is believed that the amendments and response presented herein show that the claims are in condition for allowance. In view of the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

§ 102 Rejection over Foley et al. Should Be Withdrawn

In the current Office Action, claims 37, 41, 43-46, 48, 55, 57-60, 64 and 65 were rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Application Publication 2002/0026197 to Foley et al. It is axiomatic that a reference must teach every element of the claim in order to anticipate the claim. See MPEP § 2131. Independent claim 37 recites "an expandable device including a cavity, the expandable device being removably mountable to the expandable element." Foley does not teach such a feature.

The current Office Action views Foley's item 232a as the "expandable device" of claim 37, items 254, 256 to be the claim's "expandable elements," and item 222 to be the recited "delivery instrument." Item 222 is an "elongate member" with a rod 230 and a sleeve 232 with slits in it, and items 254 and 256 are flexible strips of material that can bend outward when item

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 7 of 15
Atty. Docket 4002-3430

222 is compressed. Item 232a is the end of item 232. Claim 37 recites that the expandable device is removably mountable to the expandable element, and the expandable element is in the cavity of the expandable device. For Foley to meet that recitation, under the Office Action's view, item 232a must be removably mountable to strips 254 and 256, and items 254 and 256 must be in a cavity in 232a. As shown in Foley's Figures 7 and 8, item 232a is strips 254 and 256 (see also paragraph 0058, lines 1-7). It is not logical to say something is removably mountable to itself. It is also noted that sleeve 232 cannot be removably mounted to rod 230, because the Foley device relies on a permanent hold (crimping, welding and adhesion are noted in paragraph 0057) between the two at end 270. If that connection is removed, pushing sleeve 232 will simply push it off of rod 230, rather than flexing strips 254 and 256.

Further, the Office Action does not make any statement concerning a "cavity" in Foley, and thus it does not address all features of claim 37. Assuming for the sake of argument that the space between strips 254 and 256 is such a "cavity," it is clear that neither of items 254 and 256 are in the cavity. In fact, they define the putative cavity. For at least these reasons, Foley does not anticipate claim 37.

Dependent claims 43-46 and 48 are dependent from claim 37, and are allowable on that basis and/or on their own merit. Initially, it is respectfully noted that the Office Action did not clearly explain how the reference applies to these dependent claims, and specify the rejected claims and their features alleged to be shown in it, as required by 37 CFR 1.104(c)(2). In particular, no feature of any of claims 43-46 or 48 were discussed in any way with respect to the Foley reference. Without any such discussion, no *prima facie* case of anticipation of these claims has been made.

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 8 of 15
Atty. Docket 4002-3430

Claim 43 recites that the first and second portions of the "expandable device" are unidirectionally movable away from one another upon expansion of the expandable element. It is not possible to address what might be "first and second portions" of item 232a, since the Office Action did not provide any explanation. However, if items 254 and 256 are considered expandable elements, as the Office Action suggested, there are no other "first and second portions" of item 232a that move away from each other upon expansion of items 254 and 256. In other words, any expansion of items 254 and 256 do not cause two parts of anything else to move away from each other.

Claim 44 recites that the first and second portions of the expandable device have different heights between their distal ends than between their proximal ends. As noted above, items 254 and 256 cannot logically be called the "first and second portions," and even if they could, their proximal and distal ends are at the same height, abutting rod 230, as seen in Foley's Figures 7 and 8.

Claims 45 and 46 depend from claim 44, and recite that the expandable device have a taper between the separate heights, or a step between the first and second heights. As already demonstrated, there are no different heights at the ends of strips 254 and 256, and thus no taper or step between them.

Independent claim 55 recites, among other things, a "delivery instrument including a non-rigid expandable element," and an "expandable device including a cavity between substantially rigid first and second portions." The expandable element is expandable in the cavity to move the first and second portions away from one another. Again, the Office Action assumes that item 232a is the "expandable device," items 254 and 256 the "expandable element," and item 222 the "delivery instrument." However, item 232a cannot be the recited expandable device, because it

RESPONSE TO NON-FINAL OFFICE ACTION

Application Ser. No. 10/717,693

Page 9 of 15

Atty. Docket 4002-3430

does not have a cavity between substantially rigid first and second portions. The Office Action supposes that items 254 and 256 are "non-rigid expandable elements" as recited in the claim. It cannot logically also assert those items as rigid first and second portions. Moreover, as discussed above with respect to claim 37, items 254 and 256 cannot be both an expandable element and an expandable device, because claim 55 recites that the expandable element be expandable in the cavity in the expandable device. It is illogical to suggest that items 254 and 256 can be expandable in a cavity between themselves. Similarly, if the items 254 and 256 are the expandable elements, it is clear that Foley does not show or suggest that they move other pieces away from each other.

Dependent claims 57-60 and 64-65 are dependent from claim 55, and are allowable on that basis and/or on their own merit. Once again, it is respectfully noted that the Office Action did not clearly explain how the reference applies to these dependent claims, and specify the rejected claims and their features alleged to be shown in it, as required by 37 CFR 1.104(c)(2). In particular, no feature of any of these dependent claims were discussed in any way with respect to the Foley reference. Without any such discussion, no *prima facie* case of anticipation of these claims has been made.

Claim 57 recites that the first and second portions of the "expandable device" remain movably engaged with each other during expansion of the expandable element. As discussed previously, if items 254 and 256 are considered expandable elements, there are no other "first and second portions" of item 232a identified by the Office Action that are interrelated as specified in the claim during expansion of items 254 and 256. Claims 58-60 include language similar to that of claims 44-46, discussed above, and are not anticipated by Foley for the reasons previously given.

RESPONSE TO NON-FINAL OFFICE ACTION

Application Ser. No. 10/717,693

Page 10 of 15

Atty. Docket 4002-3430

§ 102 Rejection over Sertich Should Be Withdrawn

The current Office Action also rejected claims 37, 41-52 and 55-63 under 35 USC 102(b) as being allegedly anticipated by U.S. Patent 5,800,550 to Sertich. Independent claim 37 recites "an expandable device including a cavity." Similarly, independent claim 55 recites "an expandable device including a cavity between substantially rigid first and second portions." Sertich does not teach either of these limitations.

The current Office Action views Sertich's item 32 as the recited expandable device in claims 37 and 55, and that item 44 is the recited cavity in it. Its item 112 is asserted to be an expandable element; and item 98 the recited delivery instrument. In Sertich, its support body 30 comprises various walls, including top wall 32. Though the Office Action is not clear, it appears that the Examiner is suggesting that either top wall 32 and/or support body 30 is expandable. However, there is no teaching in Sertich that supports such a characterization.

The only discussion related to the physical nature of support body 30 indicates that "the support bodies, or interbody fusion cages, 30 function as struts and are used to maintain intravertebral disc spacing" (column 5, lines 29-31). The solidness and rigidity of support body 30 is therefore emphasized, as opposed to any expandability. Absent from Sertich is any disclosure related to the support body 30 being expandable in nature. While Sertich may suggest the widening or expansion of a space between tissues, it does not and cannot show or suggest widening or expansion of the device between the tissues. Thus, Sertich does not disclose an expandable device as claimed.

Because Sertich does not teach every limitation of claims 37 and 55, these claims are not anticipated. As to the dependent claims 42-52 and 56-62, they are allowable over Sertich based on their dependency from claims 37 and 55 and/or on their own merit. Further, it is again

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 11 of 15
Atty. Docket 4002-3430

respectfully noted that the Office Action did not discuss any feature at all of any of the purportedly rejected dependent claims with respect to Sertich, as required by 37 CFR 1.104(c)(2). Without any such discussion, no *prima facie* case of anticipation of these claims has been or can be made.

§ 102 Rejection over Felt et al. Should Be Withdrawn

The current Office Action also rejected claims 37-40 under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Patent 6,306,177 to Felt et al. Independent claim 37 recites "an expandable device including a cavity, ... wherein the expandable device is deliverable to an intravertebral space in the unexpanded condition and thereafter expandable with expansion of the expandable element to compress cancellous bone in the intravertebral space."

The current Office Action views Felt's item 26 as an expandable device 26 that is removably mountable to its item 12, which is asserted to correspond to the recited expandable element. The Applicants respectfully submit that the relied-on disclosure does not include an expandable device as claimed in claim 37. As shown in Figure 2, sheath 26 serves an application function related to the delivery of a deflated balloon 12 (see also column 33, lines 33-35). In use, once the sheath and balloon are placed into position, "sheath [26] can be withdrawn in order to release the balloon" (column 36, lines 7-9). There is no discussion or other disclosure regarding expansion, or unexpanded/expanded conditions, of sheath 26. Thus, Felt does not anticipate an expandable device as claimed.

Because Felt does not teach every limitation of claim 37, it is not anticipated. As to the dependent claims 38-40, they are allowable over Felt based on their dependency from claim 37 and/or on their own merit. Further, it is again respectfully noted that the Office Action did not

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 12 of 15
Atty. Docket 4002-3430

discuss any feature at all of any of the purportedly rejected dependent claims with respect to Felt, as required by 37 CFR 1.104(c)(2). Without any such discussion, no *prima facie* case of anticipation of these claims has been or can be made.

§ 102 Rejection over Zhong et al. Should Be Withdrawn

In the current office action, claims 37-41, 43, 48-49, 55, 57, 64 and 65 were rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Patent 6,635,078 to Zhong et al. Independent claims 37 and 55, as amended, recite "bone filler material positioned in the cavity between the first and second portions." Zhong does not show or suggest either limitation.

The current Office Action views Zhong's item 112 as an expandable device that is removably mountable to its item 108, asserted to be an expandable element. However, absent from Zhong is any disclosure or suggestion related to bone filler material positioned as recited in claims 37 and 55. Further, Zhong's device is disclosed in connection with stent placement in a blood or other bodily vessel, and use of such bone filler material would block passage through the vessel, which a stent is meant to keep open. One of ordinary skill would not understand from Zhong the disclosure of such bone filler material, and thus Zhong does not anticipate claims 37 or 55. Additionally, one of ordinary skill would not be motivated to use bone filler material with Zhong's device because doing so would prevent or impede its use and operation in the manner described in the reference. Bone filler material is neither expressly nor inherently described in Zhong, and it is also goes against the principles of the reference.

Because Zhong does not teach every limitation of claims 37 and 55, those claims are not anticipated. Dependent claims 38-40, 43 and 48-49, 57, and 64-65 are dependent from claim 37 or claim 55, and are allowable on that basis and/or on their own merit. It is again respectfully

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 13 of 15
Atty. Docket 4002-3430

noted that the Office Action did not discuss any feature at all of any of the purportedly rejected dependent claims with respect to Zhong, as required by 37 CFR 1.104(c)(2). Without any such discussion, no *prima facie* case of anticipation of these claims has been or can be made.

Claim 43 recites that the first and second portions of the expandable device are unidirectionally movable away from each other upon expansion of the expandable element. No "first and second portions" are seen in Zhong. Even if some parts of item 112 could be considered such portions, any expansion of item 26 would not occur uni-directionally, but would expand stent 112 outward in all directions. Claim 65 recites that the expandable device has a width between sides that remains substantially constant in the expanded and unexpanded conditions. Zhong's stent 112, on the other hand, expands outward in all directions, meaning that there is no width of Zhong's stent that remains constant between its expanded and unexpanded conditions..

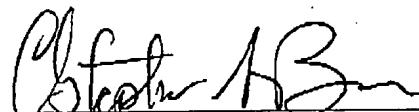
Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion. Applicant reserves the right to later contest positions taken by the examiner that are not specifically addressed herein.

Reconsideration and passage to allowance in view of the above remarks is respectfully requested. Should it be determined that any further issues are outstanding, Examiner Ramana is encouraged to telephone the undersigned.

RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 14 of 15
Atty. Docket 4002-3430

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RESPONSE TO NON-FINAL OFFICE ACTION
Application Ser. No. 10/717,693
Page 15 of 15
Atty. Docket 4002-3430